Bio-Rad Laboratories
Liquichek Hematology-16 Control LV
Premarket Notification Section 510(k)

K 091303

AUG 0 2 2010

1.0 **Submitter**

Bio-Rad Laboratories
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Contact Person

Suzanne S. Parsons
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Date of Summary Preparation

July 30, 2010

2.0 **Device Identification**

Product Name:	Liquichek Hematology-16 Control LV
Common Name:	Hematology and Pathology Devices Hematology quality control mixture
Classification:	Class II
Product Code:	JPK
Regulation Number:	21 CFR 864.8625

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Hematology-16 Control (formerly known as TRI-COUNT 16)
Bio-Rad Laboratories (formerly known as Hematronix, Inc.)
Benicia, CA 94510

510 (k) Number: K902389

4.0 **Description of Device**

This product is a suspension of stabilized lysable human erythrocytes, simulated platelet components, simulated white cells and constituents of animal origin in a medium containing stabilizers and preservatives.

5.0 **Intended Use**

Liquichek Hematology-16 Control LV is intended for use as an assayed hematology control to monitor the precision of hematology analyzers that measure the following parameters: GRAN (Granulocytes), HCT (Hematocrit), HGB (Hemoglobin), LYMPH (Lymphocytes), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), MCV (Mean Corpuscular Volume), MID (Mid-Sized Cells),

MONO (Monocytes), MPV (Mean Platelet Volume), PLT (Platelets), RBC Red Blood Cells), RDW (Red Blood Cell Distribution Width), and WBC (White Blood Cells).

6.0 Comparison of the new device with the Predicate Device

Liquichek Hematology-16 Control LV claims substantial equivalence to the Liquichek Hematology-16 Control currently in commercial distribution (K902389).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-RadLaboratories Liquichek™ Hematology-16 Control LV (New Device)	Bio-Rad Laboratories Liquichek™ Hematology-16 Control (Formerly known as TRI-COUNT 16) (Predicate Device K902389)
Similarities		
Intended Use	Liquichek Hematology-16 Control LV is intended for use as an assayed hematology control to monitor the precision of hematology analyzers that measure the following parameters: GRAN (Granulocytes), HCT (Hematocrit), HGB (Hemoglobin), LYMPH (Lymphocytes), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), MCV (Mean Corpuscular Volume), MID (Mid-Sized Cells), MONO (Monocytes), MPV (Mean Platelet Volume), PLT (Platelets), RBC Red Blood Cells), RDW (Red Blood Cell Distribution Width), and WBC (White Blood Cells).	Liquichek Hematology 16 Control is a hematology reference control used in monitoring determinations of blood cell values on cell counters.
Form	Liquid	Liquid
Matrix	suspension contains blood cells	suspension contains blood cells
Preservatives	Contains preservatives	Contains preservatives
Storage (Unopened)	2°C to 8°C	2°C to 8°C
Open Vial Claim	21 days at 2 to 8°C	21 days at 2°C to 8°C
Analytes	Contain the following parameters GRAN (Granulocytes) HCT (Hematocrit) HGB (Hemoglobin) LYMPH (Lymphocytes) MCH (Mean Corpuscular Hemoglobin) MCHC (Mean Corpuscular Hemoglobin Concentration) MCV (Mean Corpuscular Volume) MID (Mid-Sized cells) / MONO (Monocytes) MPV (Mean Platelet Volume) PLT (Platelets) RBC (Red Blood Cells) RDW (Red Blood Cells Distribution Width) WBC (White Blood Cells)	Contain the following parameters GRAN (Granulocytes) HCT (Hematocrit) HGB (Hemoglobin) LYMPH (Lymphocytes) MCH (Mean Corpuscular Hemoglobin) MCHC (Mean Corpuscular Hemoglobin Concentration) MCV (Mean Corpuscular Volume) MID (Mid-Sized cells) / MONO (Monocytes) MPV (Mean Platelet Volume) PLT (Platelets) RBC (Red Blood Cells) RDW (Red Blood Cells Distribution Width) WBC (White Blood Cells)
Differences		
Fill Volume	1.5 mL	3.0 mL
Vial Type	Glass vials	Glass tubes with pearceable caps

7.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the open vial stability and shelf life for this control. Product claims are as follows:

7.1 Open vial Stability:

All analytes will be stable for 21 days at 2 to 8°C.

7.2 Shelf Life Stability: 160 days at 2-8°C

8.0 Statement of Supporting Data

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Bio-Rad Laboratories
Ms. Suzanne Parsons
Regulatory Affairs Representative
9500 Jeronimo Road
Irvine, California 92618

AUG 0 2 2010

Re: k091303
Trade/Device Name: Liquichek Hematology-16 Control LV
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control
Regulatory Class: Class II
Product Code: JPK
Dated: July 23, 2010
Received: July 26, 2010

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

AUG 02 2010

510(k) Number (if known): K091303

Device Name: **Liquichek Hematology-16 Control LV**

Indications For Use: **Liquichek Hematology-16 Control LV is intended for use as an assayed hematology control to monitor the precision of hematology analyzers that measure the following parameters: GRAN (Granulocytes), HCT (Hematocrit), HGB (Hemoglobin), LYMPH (Lymphocytes), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), MCV (Mean Corpuscular Volume), MID (Mid-Sized Cells), MONO (Monocytes), MPV (Mean Platelet Volume), PLT (Platelets), RBC Red Blood Cells), RDW (Red Blood Cell Distribution Width), WBC (White Blood Cells).**

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K091303